ACHELON LIDOCAINE PATCH- lidocaine patch 4% patch Achelon, Inc

Achelon Lidocaine 4% Patch; 1 Patch per Pouch

Active Ingredients

Lidocaine 4%

Purpose

Topical Analgesic

Uses

For the temporary relief of pain.

Warnings

For external use only.

Do not use

Do not use

- on raw or blistered skin
- on the eyes
- if alergic to lidocaine or any ingredient in the patch
- more than 4 daily
- with a heating pad

When using this product

- Use only as directed
- Do not inject through any patch material

Stop use or ask a doctor if

If you develop a rash or skin irritation

If pregnant or breast feeding

ask a health professional before use.

Keep out of reach of children and pets

If swallowed get medical help or contact a Poison Control Center right away

Directions

Adults and children 2 years of age or older:

- Apply the patch to clean dry skin 60 minutes before procedure
- Immediately prior to procedure, remove the center of the patch, leaving ring in place to outline treated area
- Follow usual needle procedure steps
- Remove ring after procedure

Children under 2 years of age:

Consult a doctor prior to use

Other information

• store at 68 ° - 77 ° F (20 ° - 25 ° C)

Inactive Ingredients

Acrylic adhesive, Polyethylene film, Mylar release liner, Polyethylene Glycol, Levulinic acid, BrijL4LQ, Isopropyl Palmitate

Achelon Lidocaine 4%, One Patch in Indivdual Pouch





ACHELON LIDOCAINE PATCH

lidocaine patch 4% patch

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84209-400		
Route of Administration	TOPICAL				

	dient/Active Moiety					
	Ingredient Name	Basis of Strength	Strength			
LIDOCAINE (UNII:	98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	OCCAINE 7.54 mg in 60.81 cm2			
Inactive Ingr	edients					
Ingredient Name						
LEVULINIC ACID	(UNII: RYX5QG61EI)					
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)						
ACRYLIC ACID/ETHYLENE COPOLYMER (600 MPA.S) (UNII: 1PEZ 3NLY6I)						
SOPROPYL PAL	MITATE (UNII: 8CRQ2TH63M)					
Packaging						
	Package Description	Marketing Star Date	t Marketing End Date			
# Item Code	Package Description 60.81 cm2 in 1 POUCH; Type 0: Not a Combin Product	Date	-			
# Item Code 1 NDC:84209-	60.81 cm2 in 1 POUCH; Type 0: Not a Combin	Date	-			
 # Item Code 1 NDC:84209- 400-01 	60.81 cm2 in 1 POUCH; Type 0: Not a Combin	Date	-			
 # Item Code 1 NDC:84209- 400-01 	60.81 cm2 in 1 POUCH; Type 0: Not a Combin Product	ation 03/26/2025	Date			

Labeler - Achelon, Inc (080928345)

Registrant - Akron Coating & Adhesives (186566932)

Establishment							
Name	Address	ID/FEI	Business Operations				
Akron Coating & Adhesives		186569323	manufacture(84209-400)				

Revised: 3/2025

Achelon, Inc